



CERTIFICATE OF ANALYSIS

This certificate is provided to confirm that the diagnostic kit specified below conforms to the production and testing specifications required by Cepheid’s Quality System, in compliance with the US Food and Drug Administration’s Quality System Requirements and ISO 13485.

Product Name: Xpert® Xpress CoV-2/Flu/RSV plus

Instructions for Use (IFU)

Catalogue Part No.: XPRS4PLEX-10

Part No. and Rev.:

302-8057 Rev. A

Kit Lot No.: 1001459053

Cartridge Lot No.: 64101

Kit Expiration Date: 2025 11 23

Legal Manufacturer

Cepheid
904 Caribbean Drive
Sunnyvale, CA
94089 USA

Manufacturing Facility

Cepheid
121 N Guild Avenue
Lodi, CA 95240
USA

Solna


Sunnyvale

Lodi

Functional Testing according to D47377, Rev. L

<i>Test Description</i>	<i>Acceptance Criteria</i>	<i>Test Result</i>
Negative	SARS-CoV-2 NEGATIVE;Flu A NEGATIVE;Flu B NEGATIVE;RSV NEGATIVE	Passed
Positive	SARS-CoV-2 POSITIVE;Flu A POSITIVE;Flu B POSITIVE;RSV POSITIVE	Passed

If checked this document is produced electronically and valid without a wet signature.

 12/06/2024
Signature of Quality Assurance, Date

Name: Crystal Sysenglath

Title: Quality Systems Specialist